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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,099	08/23/2001	Rajiv Indravadan Modi	CAPH 8016US	2239

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POLSTER, J. PHILIP
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EXAMINER

MELLER, MICHAEL V

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 06/06/2002

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/935,099

Applicant(s)

MODI ET AL.

Examin r

Michael V. Meller

Art Unit

1651

-- The MAILING DATE of this c mmunicati n appears on the c ver sheet with the correspondence address --

Period f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 and 22-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 22-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/045,890.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Specification

The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

The following order or arrangement is preferred in framing the specification and, except for the reference to "Microfiche Appendix" and the drawings, each of the lettered items should appear in upper case, without underlining or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) Title of the Invention.
- (b) Cross-References to Related Applications.
- (c) Statement Regarding Federally Sponsored Research or Development.
- (d) Reference to a "Microfiche Appendix" (see 37 CFR 1.96).
- (e) Background of the Invention.
 - 1. Field of the Invention.
 - 2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) Brief Summary of the Invention.
- (g) Brief Description of the Several Views of the Drawing(s).
- (h) Detailed Description of the Invention.
- (i) Claim or Claims (commencing on a separate sheet).
- (j) Abstract of the Disclosure (commencing on a separate sheet).
- (k) Drawings.
- (l) Sequence Listing (see 37 CFR 1.821-1.825).

The references listed on pages 5-7 should be placed after the specification ends, i.e, at the end of page 23.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 22 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not provide support for the anti-infective agent being betalactams or quinolones. Nowhere can such support be found in the specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-18 and 22-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, it is not clear if both the first and second ingredient could be coated. What is "the active ingredient" referring to on line 6 of claim 1 ? Which active ingredient ? How could the active ingredients be contained in a single formulation if the form was a

powder, how then could they be separated by a protective barrier ? The markush groups are confusing since they provide combinations which do not necessarily produce compositions which would make compositions as claimed.

In claim 15, it is not clear in line 5, what the tablet is physically separated by. In claim 16, it is not clear which "active ingredient" the protective barrier is to go around.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 6-8, 15-18 and 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by FR 6855.

FR describes the claimed invention. It is clear from this document that the claimed invention was known at the time the invention was made.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by FR 5247.

FR describes the claimed invention. It is clear from this document that the claimed invention was known at the time the invention was made.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-18 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over FR 5247 ('5247) in view of FR 6855 ('6855) and further in view of Black et al.

The teachings of '5247 are above. It does not teach to use specifically a microorganism such as *lactobacillus acidophilus*, the specific excipients, the ratio of anti-infective agent to microorganism and the specific coating materials claimed.

'6855 teaches that *lactobacillus acidophilus* is well known to be used as the microorganism in a composition as claimed.

Black teaches that ampicillin is well known to be used in combination with microorganisms such as *lactobacillus acidophilus* to treat human intestinal microflora as applicants have done, see abstract.

It would have been obvious to one of ordinary skill in the art to use the specific microorganism, *lactobacillus acidophilus*, in view of the fact that such is well known to be used in a similar composition as is taught by '6855. To use the specific excipients, the ratio of anti-infective agent to microorganism and the specific coating materials

claimed also would have been obvious since such materials and ratios are simply the choice of the artisan in an effort to optimize the desired results and since Black teaches that *lactobacillus acidophilus* are well known to be used with ampicillin (an antibiotic like tetracycline). To use ampicillin instead of tetracycline is also obvious since tetracycline is a well known antibiotic as is ampicillin, there use is simply the choice of the artisan. Such materials and excipients are well known in the art of pharmaceutical compositions and such ratios are simply the choice of the artisan which are quite broad anyway.

Claims 1-18 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over FR 6855 ('6855) in view of Black et al.

The teachings of '6855 are above. It does not teach to use specifically use the claimed excipients, the ratio of anti-infective agent to microorganism and the specific coating materials claimed.

Black teaches that ampicillin is well known to be used in combination with microorganisms such as *lactobacillus acidophilus* to treat human intestinal microflora as applicants have done, see abstract.

It would have been obvious to one of ordinary skill in the art to use the specific excipients, the ratio of anti-infective agent to microorganism and the specific coating materials claimed since such materials and ratios are simply the choice of the artisan in an effort to optimize the desired results and since Black teaches that *lactobacillus acidophilus* are well known to be used with ampicillin (an antibiotic like tetracycline). To use ampicillin instead of tetracycline is also obvious since tetracycline is a well known

antibiotic as is ampicillin, there use is simply the choice of the artisan. Such materials and excipients are well known in the art of pharmaceutical compositions and such ratios are simply the choice of the artisan which are quite broad anyway.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 703-308-4230. The examiner can normally be reached on Monday thru Friday: 9:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Michael V. Meller
Examiner
Art Unit 1651

MVM
June 4, 2002